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JFW

July 16, 2004

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/766106
For: *METHODS AND COMPOSITIONS FOR ENHANCED DELIVERY OF
BIOACTIVE MOLECULES*
Inventors: Lewis, Danny *et al.*
Filed: January 27, 2004
Our Ref. No.: PRJ-006CN

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB-08;
3. Copies of selected references cited in PTO Form SB-08 (6); and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

July 16, 2004

Date

Jane E. Remillard, Esq., Reg. No. 38,872

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Jane E. Remillard, Esq.
Registration No. 38,872
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Lewis, Danny *et al.*

Serial No.: 10/766106

Filed: January 27, 2004

For: *METHODS AND COMPOSITIONS FOR
ENHANCED DELIVERY OF BIOACTIVE
MOLECULES*

Attorney Docket No.: PRJ-006CN

Group Art Unit: 1615

Examiner: Azpuru, Carlos A.

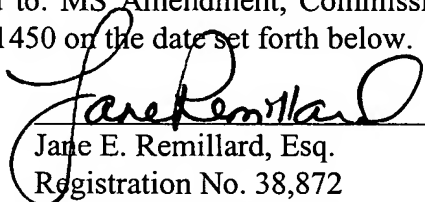
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P.O. Box 1450
Alexandria, Virginia 22313-1450

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July 16, 2004
Date of Signature and of Mail Deposit

By:


Jane E. Remillard, Esq.
Registration No. 38,872
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB-08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration.

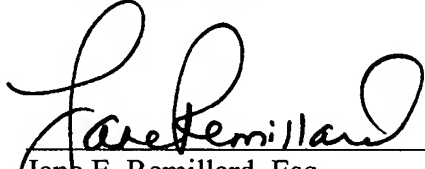
The present application is a Continuation Application of U.S. Serial No. 09/999820, filed October 31, 2001 (Atty. Docket No. PRJ-006). The majority of the references listed on the enclosed PTO Form SB-08 have been previously cited by or submitted to the Office in the prior application and, in accordance with 37 CFR §1.98(d), copies of references A1-A10, A13-A16, B5 and B6 are not enclosed, but will

be provided upon request. The remaining references A11-A12, and B1-B4 have not been previously cited and are enclosed herewith.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP


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Date: July 16, 2004

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Enclosures



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/766106
				Filing Date	January 27, 2004
				First Named Inventor	Lewis, Danny
				Art Unit	1615
				Examiner Name	Azpuru, Carlos A.
Sheet	1	of	2	Attorney Docket Number	PRJ-006CN

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	5,102,872	04/92	Singh <i>et al.</i>	
	A2	5,672,662	09/97	Harris <i>et al.</i>	
	A3	4,179,337	12/79	Davis <i>et al.</i>	
	A4	5,320,840	06/94	Camble <i>et al.</i>	
	A5	5,446,090	08/95	Harris	
	A6	5,880,255	03/99	Delgado <i>et al.</i>	
	A7	5,942,253	08/99	Gombotz <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	A8	WO 98/46212 A1	10/98	Amgen Inc.		
	A9	WO 02/41829 A2 A3	05/02	Dunn James M. <i>et al.</i>		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A10	Bently, <i>et al.</i> "PEG Biphalin: A Potent Long-Acting Analgesic" <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 28:1287-1288 (2001);	
	A11	Diwan <i>et al.</i> "Pegylation enhances protein stability during encapsulation in PLGA microspheres." <i>J. Controlled Release</i> , 73:233-244(2001);	
	A12	Diwan <i>et al.</i> "Stabilization of Recombinant Interferon-alpha by Pegylation for Encapsulation in PLGA Microspheres." <i>Int. J. Pharm.</i> 252 :111-122 (2003);	
	A13	Hora, <i>et al.</i> "Controlled Release of Interleukin-2 from Biodegradable Microspheres" <i>BIO/TECHNOLOGY</i> 8: 755-758 (August 1990).	
	A14	Hora, <i>et al.</i> "Development of a Controlled Release Microsphere Formulation of Interleukin-2" <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> 16:509-510 (1989);	
	A15	Katre, <i>et al.</i> "Chemimcal Modification of Recombinant Interleukin 2 by Polyethylene Glycol Increases its Potency in the Murine Meth A Sarcoma Model" <i>Proc. Natl. Acad. Sci. USA</i> 84:1487-1491 (1987);	
	A16	Katre, <i>et al.</i> "Immunogenicity of Recombinant IL-2 Modified by Covalent Attachment of Polyethylene Glycol" <i>J. Immunol.</i> 144:209-213 (1990);	
Examiner Signature		Date Considered	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.



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				Examiner Name	Azpuru, Carlos A.
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶

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Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	B1	Kim <i>et al.</i> "Controlled release of PEGylated peptides from poly(lactic-co-glycolic acid) microspheres." <i>Proceed. Int'l Symp. Control. Rel. Bioact. Mater.</i> 28 : #6175 (2001);	
	B2	Kim <i>et al.</i> "Pegylated recombinant human epidermal growth factor (rhEGF) for sustained release from biodegradable PLGA microspheres." <i>Biomaterials</i> 23:2311-2317 (2002);	
	B3	Lam <i>et al.</i> "Sustained release of PEGylated monoclonal antibody fragments from drug delivery systems." <i>Proceed. Int'l Symp. Control. Rel. Bioact. Mater.</i> 29 : #037 (2002);	
	B4	Lam <i>et al.</i> "Integrity of PEGylated monoclonal antibody fragment in polymeric matrices." <i>Proceed. Int'l Symp. Control. Rel. Bioact. Mater.</i> 30 : #449 (2003);	
	B5	Misicka, <i>et al.</i> "Structure-Activity Relationship of Biphalin. The Synthesis and Biological Activities of New Analogues with Modifications in Positions 3 and 4." <i>Life Sciences</i> 60(15):1263-1269 (1997);	
	B6	Yip, <i>et al.</i> "Direct Force Measurements of Insulin Monomer—Monomer Interactions" <i>Biochemistry</i> 37(16):5439-5449 (1998).	
Examiner Signature		Date Considered	

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